

REMARKS

Applicants' Claim for Priority Under 35 USC 119

Concerning item no. 12 on page 1 of the Office Action, the Examiner is respectfully requested to indicate on the record that the certified copy of the priority document has been received in this national stage application from the International Bureau.

Title

The title was amended hereinabove to conform to the presently claimed invention.

Objections to the Abstract and the Specification

1. The abstract was objected to for the reason set forth on page 5 of the Office Action.

The abstract was amended to avoid the objection. The abstract was also amended to conform to the presently claimed invention.

2. The specification was objected to for the reasons set forth beginning at the bottom of page 5 and continuing to the middle of page 6 of the Office Action.

This objection concerns the first paragraph on page 72 of the specification, which recites "0.0001 mg/kg to 1.0 mg/kg, and preferably 0.001 mg/kg/**day** to 0.1 mg/kg."

The specification was amended hereinabove to replace "mg/kg/day" with --mg/kg-- in the first paragraph on page 72 of the specification. In view of the other recitations of "mg/kg" in the first paragraph on page 72 of the specification, it is respectfully submitted that this amendment is an obvious correction of an obvious error.

Withdrawal of each of the objections to the abstract and the specification is respectfully requested.

Claim Amendments

Claim 1 was amended to recite the compound of Example 1, the structure of which is set forth in line 25 of page 72 and the last line on page 116 of the specification.

In view of the above amendment to claim 1, claims 2 to 6, 20 and 42 were canceled hereinabove.

A minor editorial revision was made to claim 8.

Claim 18 was amended to conform to the above-described amendment to page 72 of the specification.

Withdrawn claims 19 and 21 to 41 were canceled. Applicants reserve their rights to file a Divisional application pursuant to 35 USC 121 to the withdrawn claims 19 and 21 to 41.

New claim 43 recites the hydrochloride salt of the compound recited in amended claim 1, which is supported on page 72, lines 20 to 21 of the specification.

New claim 44 recites the dosage features recited in claims 8 and 18.

Obviousness Rejection Under 35 USC 103

Claims 1 to 6, 8, 18, 20 and 42 were rejected under 35 USC 103 as being unpatentable over Nishi et al. (WO 03/059880) and US 2005/0043386 in view of Budd et al. (US 2002/0086832) for the reasons set forth beginning at the middle of page 7 and continuing to the middle of page 9 of the Office Action.

It was admitted in the Office Action that Nishi et al. fail to disclose a method for suppressing the number of peripheral blood lymphocytes, as recited in applicants' present claims. Nishi et al. do not teach or suggest that the compound recited in applicants' present claim 1 would be useful for suppressing the number of blood lymphocytes.

Budd et al. concern the use of inhibitors of cysteine aspartate proteins (caspases) for treating diseases or disorders caused by hyperproliferation of peripheral blood lymphocytes.

Budd et al. do not teach or suggest the compound recited in applicants' present claims.

It is respectfully submitted that the Office Action has not provided any plausible reason why one of ordinary skill in the art would have substituted a compound as disclosed by Nishi et al. in the method of Budd et al., since Budd et al. uses compounds that are totally different than the Nishi et al. compounds.

It is therefore respectfully submitted that for the reasons discussed hereinabove, the cited prior art (1) would not have suggested to those of ordinary skill in the art that they could make applicants' presently claimed invention and (2) would not have revealed to those of ordinary skill in the art a reasonable expectation of success. Therefore, following the teaching-suggestion-motivation ("TSM") test would lead to the conclusion that applicants' presently claimed invention patentably distinguishes over the cited prior art.

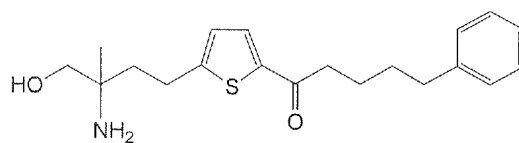
Furthermore, it is respectfully submitted that applicants' presently claimed invention is patentable, based on the experimental data set forth in applicants' specification. Specifically, Test Examples 1 and 2 on pages 113 to 116 of the present specification show experimental data demonstrating the

following: (i) superior results for the presently claimed invention, compared to Comparative Compounds 1 and 2 disclosed in the prior art and (ii) superior pharmacokinetics for the presently claimed invention.

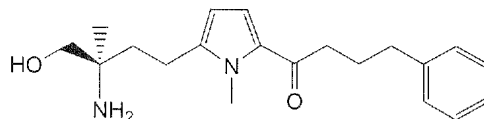
The table at the top of page 114 of the present specification is reproduced (in part) as follows:

Measurement of Peripheral Blood Lymphocyte Count

Compound	Lymphocyte Count (Relative Value Based on a value of 100% for Normal Control Group) (%)
Example 1 (according to the presently claimed invention)	8
Comparative Compound 1	30
Comparative Compound 2	31



Comparative Compound 1



Comparative Compound 2

As seen from the above table, the compound of the presently claimed invention demonstrates superior activity, compared to the comparative compounds.

The table at the top of page 115 of the present specification is reproduced (in part) as follows:

Measurement of ID₅₀ of Rat Peripheral Blood Lymphocyte Count (mg/kg)

Compound	ID ₅₀ (mg/kg)
Example 1 (according to the presently claimed invention)	0.21
Comparative Compound 2	0.78

The table at the top of page 116 of the present specification demonstrates that the compound of Example 1, as recited in the presently claimed invention, has superior pharmacokinetics.

Withdrawal of the 35 USC 103 rejection is respectfully requested.

If generic claim 1 is found allowable, it is respectfully submitted that withdrawn claims 8 and 33 be examined and allowed.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Richard S. Barth".

Richard S. Barth
Reg. No. 28,180

Holtz, Holtz, Goodman & Chick PC
220 Fifth Avenue - 16th Floor
New York, New York 10001-7708
Tel. No. (212) 319-4900
Fax No. (212) 319-5101
E-mail Address: RBARTH@HHPATENT.COM
RSB/ddf

Enclosure: INFORMATION DISCLOSURE STATEMENT